EXECUTIVE SUMMARY

PURPOSE

To assess the extent and appropriateness of pharmaceutical use by selected Texas nursing home residents and to describe pharmacists' concerns about drug use.

BACKGROUND

The primary goal of drug therapy for nursing home patients is to maintain and improve, to the extent possible, the patient's functional capacity and quality of life. The Omnibus Budget Reconciliation Acts (OBRA) of 1987 and 1990, in recognition of this, require the regulation of certain drugs in nursing homes and the establishment of drug utilization review programs for nursing home residents. Provisions of the OBRA 1990, while not required for all nursing homes, also clearly establish Congress' desire to involve pharmacists more actively in patient care. Broad oversight of the drug therapy requirements for the nursing homes is performed by consultant pharmacists hired to perform a monthly medication review for each resident. Yet, several recent studies suggest that the use of inappropriate or contraindicated drugs is a contributing factor to the high health care costs in the elderly population. It is important to understand that reports of possible "inappropriate" use of medications are somewhat a matter of opinion. Ultimately, for nursing home patients, it is either the patient's attending physician or the facility's medical director who determine what is appropriate care. This includes prescribing medications to meet patients' needs.

We undertook this inspection, using three different approaches, to provide insight into several issues related to prescription drug use in nursing homes. These issues are addressed in three reports, of which this is the third. The first report describes prescription drug use in Texas nursing facilities; the second report discusses medication use concerns expressed by a nationally representative sample of consultant pharmacists. This third report provides the results of a pharmaceutical review (conducted by independent pharmacists with whom we contracted for this purpose) of 254 sampled Texas nursing home patients. Additionally, this final report presents recommendations addressing the issues and concerns raised collectively by all three reports issued as part of this coordinated inspection.

FINDINGS

Overall, contracted pharmacists' reviews consistently identified the same problems and concerns for patients as were raised by our analysis of Texas data and the national survey of consultant pharmacists. This finding underscores the need for strengthening medication reviews and improving medication prescribing, administration, and monitoring practices in nursing homes.

Quality of Care Issues

Contracted medication reviews revealed potentially serious concerns with residents' drug regimens.

20 percent of the reviewed patient records identified patients receiving at least one drug judged inappropriate for their diagnoses. Additionally, patients' records indicated some residents were taking medications potentially contraindicated by their diet requirements, plans of care, or assessments.

16 percent of patients were receiving, without a prescription in their records, drugs for which prescriptions are generally required. Further, 23 percent of the patients were prescribed medications for which the records showed no orders or receipts to indicate the patient actually received the medication.

Approximately 20 percent of residents received at least one drug considered by experts to be inappropriate for use by the elderly.

Some patients' records indicate they may be experiencing unnecessary adverse medication reactions as a result of inadequate monitoring.

21 percent of patients were receiving drugs which may sometimes negatively interact with other drugs in their regimen.

Nearly one-third of patients were receiving more than one drug from the same class, sometimes a potential hazard. Drugs from the same class may produce similar side effects which can be additive and need to be carefully managed. Yet, 19 percent of all records indicate no monitoring for efficacy.

Shortcomings of Medication Reviews

Resident medication records are often incomplete, making it difficult or impossible to identify or confirm potential drug regimen problems.

31 percent of patients' records were not sufficiently complete to allow contract pharmacists to make determinations concerning the appropriateness of medications prescribed for patients' diagnoses.

Contract pharmacists identified several patients whose prescribed medications may have contributed to falls, depression, and constipation. However, due to insufficient records, they were unable to pinpoint or eliminate the patient's drug regimen as the cause.

Often the contract pharmacists were unable to determine whether a patient had received a monthly drug regimen review during the sampled time period.

Thorough contracted medication reviews required much more time than the usual review times reported by nursing home consultant pharmacists. Allotting more time for conducting reviews appears to help in detecting more medication concerns.

Contract pharmacists' reviews averaged 50 minutes, which is considerably longer than the times consultant pharmacists expend doing medication reviews (averaged 5-10 minutes per monthly review with initial reviews taking 15-20 minutes).

The contract pharmacists identified medication problems or concerns for 20 percent of the patients which had not been identified by the nursing home consultant pharmacists' reviews.

RECOMMENDATIONS

Medication problems and concerns raised collectively by the three coordinated reports of this inspection demonstrate the need for stronger monitoring and more positive enforcement of existing regulations and required reviews of medication usage in nursing homes. Therefore, we recommend that the Health Care Financing Administration:

- Continue to monitor and encourage reductions in the use of potentially inappropriate prescription drugs in the elderly nursing home population;
- Work with other Federal and State agencies to identify and analyze reasons for the rapid escalation in costs and claims for certain types of drugs used in nursing homes (i.e., gastrointestinal, psychotherapeutic, cardiac, cardiovascular, and anti-infectives);
- Strengthen the effectiveness and impact of medication reviews conducted by consultant pharmacists in nursing homes;
- Require nursing homes to ensure that the curriculum for required on-going, in-service training for personal care staff (nurse aides) includes information on how to recognize and report signs of possible contraindications, adverse reactions, or inappropriate responses to medications;
- Strengthen and enforce coordination and communication among the involved healthcare team members in nursing homes; and
- More vigorously pursue enforcement of resident health outcomes.

COMMENTS ON THE DRAFT REPORT

We solicited comments from agencies within the Department of Health and Human Services which have responsibilities for policies related to Medicare and Medicaid and long term care. We also requested input from several national organizations representing the interests of nursing homes, patients, or providers. We appreciate the time and efforts of those providing comments.

Departmental Comments

Within the Department, we received comments on the draft reports from the Health Care Financing Administration (HCFA) and the Assistant Secretary for Planning and Evaluation (ASPE). Both agencies concurred with the recommendations; HCFA emphasized the need for further studies to assess the extent of continued use of potentially inappropriate drugs, other avenues of possible cost savings related to drugs, and the need to determine and understand the potential sources of the escalating costs and claims for certain types of drugs used in nursing homes. The final reports reflect several clarifications or changes based on their suggestions. The full text of each agency's comments is provided in Appendix D.

Comments from External Organizations

We also received comments from the following external organizations: American Health Care Association; American Association of Homes and Services for the Aging; American Medical Directors Association; American Society of Consultant Pharmacists; and National Association of Boards of Pharmacy. Most of the associations concurred with one or more of the recommendations within each of the inspection reports. All commentors support the need for better communication and coordination between nursing home staff and other healthcare providers, training nurse aides, and understanding the implications of nursing home medication services and associated costs.

Several organizations questioned the methodology used in this inspection, particularly for the consultant pharmacist survey. However, as with any evaluation, there are always some limitations in how data and information can be obtained, given time and other resource constraints. Further, while we acknowledge that a survey of this nature introduces some bias and subjectivity, we also believe that the survey of consultant pharmacists provides us with an up-close view of what is happening with prescription drug use in nursing homes. Moreover, the results of the consultant pharmacist survey are consistent with our results from our two other methodologies.

Some comments expressed concerns about the use of the term, "inappropriate." As explained previously, use of this term in reporting concerns with a patient's medication regimen are somewhat a matter of opinion. The evidence provided in these three reports does not prove that any one prescription was improper, but that closer examination is warranted. Also, while the use of such a drug may be supported by physician orders in individual cases, use of the drug, in general, is likely to be considered inappropriate.

Some comments addressed the implications of broadening Federal oversight. There is clear concern about the responsibility for medication issues being the responsibility of the physician, not the nursing home. Further, some organizations expressed concern that these particular issues did not result in direct recommendations about the physician's role

for nursing home patients' medication regimens. We felt that further examination of this area is warranted before recommending changes which would impact so many entities involved in the process.

In conclusion, we believe the three reports collectively, and each using a different approach, strongly indicate that the intent of the provisions of the OBRA Acts concerning prescription drug usage are not being clearly fulfilled. Further, HCFA has authority to correct and enhance quality of care for nursing home patients. The recommendations we present attempt to facilitate the initial steps of this effort, and to address some concerns evidenced in the reports and received comments. While we recognize that great strides have been made to meet the OBRA requirements, we believe further effort remains by all the players involved (HCFA, associations and their members, nursing homes, and residents and their families) to further improve quality of care for nursing home patients.

The full text of each organization's comments is provided in Appendix E.